DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Stryker Leibinger GmbH & Company KG
Ms. Becky Ditty
Senior Staff Regulatory Affairs Specialist
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

September 4, 2015

Re: K143597
Trade/Device Name: Navigated XIA® 4.5 Polyaxial Screwdriver
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 5, 2015
Received: August 7, 2015

Dear Ms. Ditty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143597

Device Name
Navigated XIA® 4.5 Polyaxial Screwdriver

Indications for Use *(Describe)*
The Stryker Xia 4.5 Polyaxial Screwdriver is a Stryker Navigated Manual Surgical Instrument.

Stryker Navigated Manual Surgical Instruments are intended to be used as accessories to the Stryker Spine Navigation System, when used with the SpineMap 3D Navigation software. They are manual surgical instruments intended to be used in spine surgery to facilitate placement of Stryker Spine implants.

Stryker Navigated Spine Instruments may be used as part of the Stryker Spine Navigation System, which is indicated for any medical condition in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified.

Stryker Navigated Spine Instruments are intended for exclusive use with the Rotational Navigational Adaptor and associated Trackers to facilitate the placement of the pedicle screws of the Stryker Spine XIA® 3, XIA® 4.5, MANTIS®, MANTIS® Redux, and ES2® Spinal Fixation Systems using the STRYKER SpineMap® 3D Navigation System.

The surgeon must also refer to the Stryker Spine XIA® 3, XIA® 4.5, MANTIS®, MANTIS® Redux, or ES2® package insert/instructions for use, product label, and surgical technique guide to obtain detailed product information and recommended surgical procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

This chapter provides a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Section 5.1 Submitter

Applicant Name:	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany Phone number: +49-761-4512117 Fax number: +49-761-451249117
Registration No.:	8010177
Name of Contact Person:	Becky Ditty Sr. Staff Regulatory Affairs Specialist 4100 E. Milham Ave Kalamazoo, MI 49001 becky.ditty@stryker.com (269) 389-3434
Date Prepared:	September 4, 2015

Section 5.2 Device

Trade Name:	Navigated XIA® 4.5 Polyaxial Screwdriver				
Common Name:	Navigated Screwdriver				
Classification Name:	Product Code	Device	Regulation Number	Class	Review Panel
	Primary Code OLO	Orthopedic Stereotaxic Instrument	21 CFR §882.4560	II	Orthopedic
	Secondary Code: LXH	Orthopedic Manual Surgical Instrument	21 CFR §882.4540	I	Orthopedic

Section 5.3 Predicate Devices

Trade Name	Stryker Navigation System – Spine & Fluoroscopy Module: Stryker Adapted Smart Manual Instruments (Primary Predicate)	XIA® 4.5 Polyaxial Screwdriver
510(k) Number	K012380	N/A – Class I/ 510(k) exempt device
Product Code	HAW	LXH
Manufacturer	Stryker Leibinger GmbH & Co. KG	Stryker Spine SAS

These predicate devices have not been subject to a design-related recall.

Section 5.4 Device Description

The Navigated XIA® 4.5 Polyaxial Screwdriver, a Stryker Navigated Spine Instrument, is a manual tool for bone screw placement, insertion, and removal. The tip of the navigated screwdriver inserts into the screw head to turn it. The screwdriver also has an interface to allow a connection to the Rotational Navigation Adapter, a Stryker Spine Navigation System accessory, and to a handle.

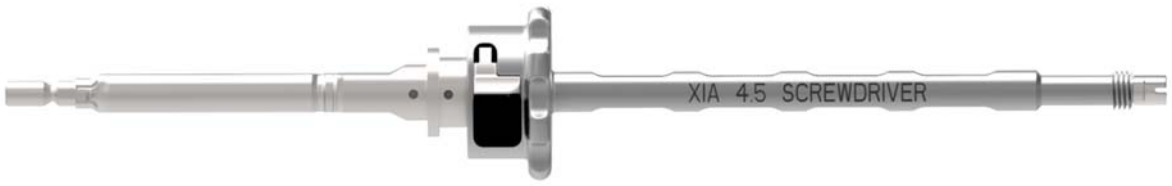

FIGURE 5-1: NAVIGATED XIA 4.5 POLYAXIAL SCREWDRIVER

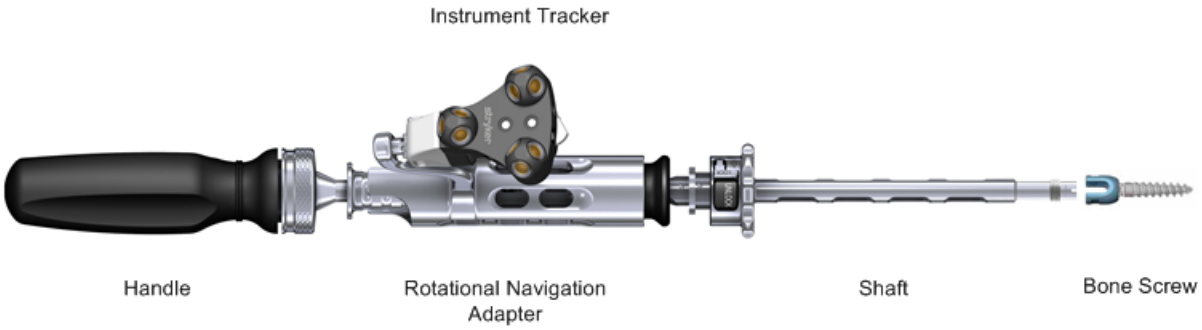

FIGURE 5-2: NAVIGATED XIA 4.5 POLYAXIAL SCREWDRIVER ATTACHED TO ROTATION NAVIGATION ADAPTER, INSTRUMENT TRACKER AND HANDLE

Section 5.5 Indications for Use

The Stryker Xia 4.5 Polyaxial Screwdriver is a Stryker Navigated Manual Surgical Instrument.

Stryker Navigated Manual Surgical Instruments are intended to be used as accessories to the Stryker Spine Navigation System, when used with the SpineMap 3D Navigation software. They are manual surgical instruments intended to be used in spine surgery to facilitate placement of Stryker Spine implants.

Stryker Navigated Spine Instruments may be used as part of the Stryker Spine Navigation System, which is indicated for any medical condition in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified.

Stryker Navigated Spine Instruments are intended for exclusive use with the Rotational Navigational Adaptor and associated Trackers to facilitate the placement of the pedicle screws of the Stryker Spine XIA® 3, XIA® 4.5, MANTIS®, MANTIS® Redux, and ES2® Spinal Fixation Systems using the STRYKER SpineMap® 3D Navigation System.

The surgeon must also refer to the Stryker Spine XIA® 3, XIA® 4.5, MANTIS®, MANTIS® Redux, or ES2® package insert/instructions for use, product label, and surgical technique guide to obtain detailed product information and recommended surgical procedure.

Section 5.6 Comparison of Technological Characteristics with the Predicate Device

The Navigated XIA 4.5 Polyaxial Screwdriver (subject device) and the predicate devices are intended to be used during the preparation and placement of Stryker Spine screws during spinal surgery, including insertion and removal of bone screws.

The subject and predicate devices have similar technologies, such that the devices interface with a handle and have a tip that the user inserts into the screw head to turn it.

Additionally, the subject device and the Stryker Adapted Smart Manual Instruments predicate device are both designed to interface with Stryker Navigation Systems via the previously cleared Stryker Spine Navigation System accessories: the Rotational Navigation Adapter (K012380) and an Instrument Tracker (K141941). The

attachment of the Rotational Navigation Adapter and Instrument Tracker to the instrument allows for the localization and navigation of the manual surgical instruments and thus the technology is not included in the subject device itself.

The subject device includes minor design changes as compared to the predicate devices. The main change is a longer shaft to enable the attachment of the Rotational Navigation Adapter; however the subject device also has a modified locking mechanism, and can interface with a wider range of handles.

The instrument modifications detailed in this submission have no impact on the technological characteristics of either the existing instruments or the Stryker Spine Navigation Systems. None of the changes identified affect how the spinal screw is placed or removed. The navigation of the manual instrument is not performed by the instrument itself, but by previously cleared Stryker Spine Navigation System accessories. The accuracy testing provided demonstrates that the Stryker Spine Navigation System accessories (Rotational Navigation Adapter and Instrument Tracker) can be sufficiently connected to the Navigated XIA 4.5 Polyaxial Screwdriver such that the accuracy requirements of the Stryker Spine Navigation System can be achieved.

Section 5.7 Performance Data

The following performance data were provided in support of the substantial equivalence decision:

Performance Testing - Bench

Test	Description
Simulated Use	Tested the Navigated XIA 4.5 Polyaxial Screwdriver together with the Stryker Spine Navigation System and its components and accessories in a cadaveric setting according to its requirements.
Navigation Accuracy	Verified the navigation accuracy of ± 2 mm and ± 2° of the Navigated XIA 4.5 Polyaxial Screwdriver by verifying its tracking accuracy of (80th percentile < ± 1.5 mm) according to ASTM F2554:2010.

TABLE 5-1: V&V OVERVIEW

Performance Testing - Animal

No animal studies were performed to support substantial equivalence.

Performance Testing - Clinical

No clinical studies were performed to support substantial equivalence.

Section 5.8 Conclusion

The non-clinical data support the safety of the device and verification and validation demonstrate that the Navigated XIA 4.5 Polyaxial Screwdriver device performs as intended in the specified use conditions. The data also demonstrates that the Navigated XIA 4.5 Polyaxial Screwdriver performs comparably to the predicate devices that are currently marketed for the same intended use.